K102438

SEP 30 2010

8. 510(k) Summary

Date:	23 August 2010
Sponsor:	OsteoMed Spine Inc.* 3885 Arapaho Road Addison, TX 75001 Phone: (972) 677-4787 Fax: (972) 677-4778 * wholly owned subsidiary of OsteoMed LP
Contact Person:	Rebecca Ellis, Vice President, RA/QA & Organizational Excellence
Proposed Trade Name:	PrimaLOK™$_{FF}$ Facet Fixation System
Device Classification	Unclassified, Pre-Amendment
Classification Name:	Facet screw spinal device system
Regulation:	–
Device Product Code:	MRW
Device Description:	The PrimaLOK™$_{FF}$ Facet Fixation System is a partially threaded, cannulated, self-tapping 4.5mm screw having an assembled, articulating washer. It is available in lengths from 25 to 45mm to accommodate differing anatomic requirements.
Intended Use:	The PrimaLOK™$_{FF}$ Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. It is intended for use with or without bone graft, at a single or multiple levels from L1 to S1 inclusive. It is indicated for the posterior surgical treatment of any or all of the following: degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, degenerative disease of the facets with instability, trauma (i.e., fracture or dislocation), spondylolisthesis, spondylolysis, and pseudarthrosis and failed fusions which are symptomatic or which may cause secondary instability or deformity. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle.
Materials:	The PrimaLOK™$_{FF}$ Facet Fixation System components are manufactured from titanium and titanium alloy (Ti-6Al-4V) as described by ASTM F67 and F136, respectively.
Predicate Devices:	Discovery® Facet Screw (DePuy AcroMed, K012773) Chameleon™ Fixation System (Spine Frontier, Inc. – K071420) PERPOS™ PLS System, BONE-LOK® Implant (Interventional Spine, Inc. – K082795)

Technological Characteristics:

The PrimaLOK™$_{FF}$ Facet Fixation System possesses the same technological characteristics as one or more of the predicates. These include:

- basic design: partially threaded, cannulated screw with washer,
- material: titanium and/or titanium alloy,
- sizing: sizes (diameter and lengths) are within the range of those offered in the predicate systems, and
- intended use: as described above

The PrimaLOK™$_{FF}$ Facet Fixation System possesses a modified technological characteristic in that the assembled washer incorporates an integral feature which provides resistance to backout.

Therefore the fundamental scientific technology of the PrimaLOK™$_{FF}$ Facet Fixation System is the same as previously cleared devices.

Performance Data:

Static and dynamic cantilever bending (modified ASTM F2193) and axial pullout tests (ASTM F543) were used to characterize the mechanical properties of the PrimaLOK™$_{FF}$ Facet Fixation System. The results demonstrated that the PrimaLOK™$_{FF}$ Facet Fixation System is substantially equivalent to predicate device performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Osteomed L.P.
% BackRoads Consulting, Inc.
Karen E. Warden, Ph.D.
8202 Sherman Road
Chesterland, OH 44026-2141

SEP 30 2010

Re: K102438
Trade Name: PrimaLOK™ FF Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: August 26, 2010
Received: August 27, 2010

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may; therefore market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

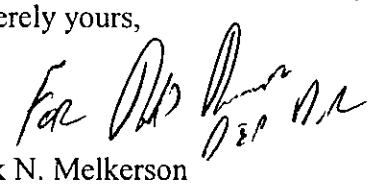
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102438

7. Indications for Use Statement

510(k) Number: K102438

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Indications for Use:

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Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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